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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,644	10/08/2004	Akihiko Mizutani	MIZUTANI3	4955

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EXAMINER	
AHMED, HASAN SYED	
ART UNIT	**PAPER NUMBER**
1615	

MAIL DATE	DELIVERY MODE
07/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,644	MIZUTANI ET AL.	
	Examiner	Art Unit	
	Hasan S. Ahmed	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-17* is/are pending in the application.

4a) Of the above claim(s) *10-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,3-9 and 14-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicants' amendment, which was filed on 17 April 2007.

* * * * *

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 3-9, 14, and 15 rejected under 35 U.S.C. 102(e) as being anticipated by Iida et al (U.S. Patent No. 6,893,658).

Iida et al. disclose a light stable soft capsule formulation (*see* col. 3, lines 7-18) comprising:

- the shell containing a non-water soluble light-shielding agent of instant claim 1 (*see* col. 2, lines 1-7);

- the 5 to 30 wt% of the non-water-soluble light-shielding agent of instant claim 1 (up to 6% according to the formulations recited in the instant application; *see* response to arguments, below) (see col. 3, lines 21-23);
- the 200 μm thickness of instant claim 1 (*see* claim 1);
- the medicament encapsulated by the shell of instant claim 1 (*see* col. 2, line 49);
- the titanium oxide of instant claim 3 (*see* col. 3, lines 7-18);
- the seamless shell of instant claim 5 (*see* col. 5, lines 18-40);
- the light-unstable medicament of instant claim 6 (*see* col. 2, line 49);
- the medicament suspended in a liquid base of instant claim 7 (*see* col. 5, line 10);
- the vitamin D derivative of instant claim 8 (*see* col. 2, line 49);
- the gelatin of instant claim 9 (*see* col. 4, line 16)'
- the unit dose of instant claim 14 (see col. 1, lines 5-6); and
- the capsule of instant claim 15 (see col. 1, lines 5-6).

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-9, and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iida et al (U.S. Patent No. 6,893,658).

Iida et al. disclose a light stable soft capsule formulation (*see* above).

Iida et al. explain that the disclosed formulation is beneficial because it provides "excellent stability to light and heat and good discrimination." *See* col. 2, lines 39-40.

While Iida et al. do not explicitly teach the percentages of instant claims 16 and 17, or the capsule size of instant claim 4, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages and size through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration and size will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage range or size.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a light stabilized soft capsule formulation comprising a shaell containing titanium oxide, and a vitamin D derivative encapsulated in the shell, as taught by Iida et al. One of ordinary skill in the art at the time the invention was made

would have been motivated to make such a composition because it results in excellent stability to light and heat and good discrimination, as explained by Iida, et al.

* * * * *

Response to Arguments

Applicant's arguments filed on 17 April 2007 have been fully considered but they are not persuasive.

1. Applicants argue that the amount of titanium oxide disclosed by Iida is, "...**very low** compared with what is claimed." *See* remarks, page 8.

Contrary to applicants' argument, examiner respectfully submits that the Iida reference teaches a concentration of titanium oxide that is within the 5-30% range claimed by applicants.

Applicants claim titanium oxide at a concentration of 5-30%, based on the total amount of all components constituting the shell (*see* instant claim 1). Example 2 of the instant specification recites that a solution of 4 wt% titanium oxide contains 1 wt% titanium oxide. The Iida reference teaches titanium oxide up to 1.5% of the total amount of capsule shell components (*see* col. 3, line 23). Based on the formulation of instant Example 2, the Iida reference teaches a titanium oxide concentration of 6%, which is well within the concentration range claimed.

2. Applicants argue that the concentration of titanium oxide is, "...the required range necessary to achieve the required degree of shielding." *See* remarks, page 9.

Examiner respectfully submits that applicants are not claiming the property of shielding at all, much less any degree of shielding. The term "shielding" recited in the

claims is used only as a descriptor for the "shielding agent" titanium oxide, as opposed to a degree of light shielding. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Even if, *arguendo*, the property of light shielding were claimed, figure 4 of the instant specification clearly shows light shielding with 4% titanium oxide, which is a lower concentration than that disclosed by Iida. As such, applicants have not shown any unexpected results.

3. Applicants use the Matsuda reference to suggest that the artisan would not have used a concentration of titanium oxide above 1 wt% for the purpose of light shielding. See remarks, pages 9-11.

Examiner respectfully submits that this argument is moot in view of the Iida reference, since the latter teaches titanium oxide at concentrations above 1% (see col. 3, lines 21-23).

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

☆

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Humera N. Sheikh

HUMERA N SHEIKH
PRIMARY EXAMINER